



MUTUAL DATA USE AGREEMENT

This Mutual Data Use Agreement (“Agreement”), is entered into and made effective on this [REDACTED] [REDACTED] 2020 (“Effective Date”), by and between [REDACTED] a

[REDACTED] on behalf of its Principal Investigator, [REDACTED] and Colorado Department of Public Health and Environment Center for Health and Environmental Data, [REDACTED] with offices located at 4300 Cherry Creek Drive South, Denver, CO 80246 (“CDPHE”). [REDACTED] and CDPHE are each referred to individually as a “Party” and collectively as the “Parties”.

RECITALS:

WHEREAS, [REDACTED] is a “Covered Entity” as that term is defined in the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and is obligated and committed to complying with the Standards for Privacy of Individually Identifiable Health Information (the “Privacy Rule”) and the Standards for Security of Electronic Protected Health Information (the “Security Rule”) set forth in HIPAA and its implementing regulations;

WHEREAS, CDPHE is a “public health authority” as that term is defined in the HIPAA, and as such complies with the HIPAA privacy and security requirements to the extent feasible;


WHEREAS, [REDACTED] is conducting a research study entitled [REDACTED] [REDACTED] (the “Study”), which is described in more detail in *Appendix D*, Statement of Work, and has been approved through [REDACTED] Institutional Review Board (IRB) Protocol No. [REDACTED] (“Protocol”) which is attached hereto as *Appendix A*;

WHEREAS, as part of the Study, [REDACTED] will provide specific data elements listed in *Appendix B* that include Protected Health Information (PHI) within the meaning of HIPAA (“[REDACTED] Data”) to CDPHE;

WHEREAS, CDPHE will link [REDACTED] Data it receives to specific data elements listed in *Appendix C* that are held in its [REDACTED] including data elements constituting a Limited Data Set within the meaning of HIPAA that are the minimum necessary to achieve the purpose of the Study (“CDPHE Data”);

WHEREAS, CDPHE will provide the linked CDPHE Data to [REDACTED] for use in the Study; and

WHEREAS, this Agreement, in conjunction with the Privacy Rule and Security Rule, sets forth the terms and conditions pursuant to which [REDACTED] Data and CDPHE Data that is created, received, maintained or transmitted by either Party will be disclosed to and used in support of Study activities as set forth in the Protocol;



WHEREAS, to the extent a Party is providing ██████ Data or CDPHE Data (“Data”) to the other Party, the disclosing Party will be referred to as the “Discloser”; and

WHEREAS, to the extent a Party is receiving Data from the other Party, the receiving Party will be referred to as the “Recipient”.

1. **Use of ██████ Data.** In consideration of ██████ making available ██████ Data to CDPHE, CDPHE agrees as follows:

- (a) To use and disclose ██████ Data solely for the purposes of supporting the Study. Any further use is prohibited;
- (b) To use and disclose ██████ Data only as permitted by this Agreement or as required by law;
- (c) To permit only the following specified individuals to use or receive ██████ Data:
 - ██████
 - ██████
- (d) To use appropriate administrative, technical, and physical safeguards to prevent use or disclosure of ██████ Data other than as provided for by this Agreement and the Protocol;
- (e) To remain in compliance with all applicable U.S. federal, state, and local laws and regulations while handling or storing ██████ Data;
- (f) To promptly return or destroy ██████ Data upon confirmation from ██████ that ██████ has received the linked CDPHE Data. If CDPHE discovers at any time during the Retention Period that the return or destruction of ██████ Data is infeasible, CDPHE must notify ██████ in writing, within thirty (30) days; and
- (g) To report to ██████ and to state agencies, as appropriate, any use or disclosure of ██████ Data not provided for by this Agreement of which it becomes aware, including without limitation, any disclosure of PHI to an unauthorized subcontractor, within five (5) days.

2. **Use of CDPHE Data.** In consideration of CDPHE making available CDPHE Data to BWH, BWH agrees as follows:

- (a) To use and disclose CDPHE Data solely in furtherance of the Study. Any further use is prohibited;
- (b) To use and disclose CDPHE Data only as permitted by this Agreement or as otherwise required by law and to not use or further disclose CDPHE Data in a manner that would violate the Privacy Rule if ██████ were the Discloser;
- (c) To ensure that all persons who have access to CDPHE Data keep CDPHE Data confidential, except as necessary to publish and verify the Study’s research results derived from the use of CDPHE Data. ██████ represents and certifies that its employees sign confidentiality agreements as part of their employment.
- (d) To permit only the following specified individuals to use or receive CDPHE Data:
████████████████████

- [REDACTED]
- [REDACTED]

- (e) To use appropriate administrative, technical, and physical safeguards to prevent use or disclosure of CDPHE Data other than as provided for by this Agreement;
- (f) To report to CDPHE within three (3) days of [REDACTED] discovery of any use or disclosure, including and without limitation, any disclosure of CDPHE Data to an unauthorized subcontractor, not provided for by this Agreement of which it becomes aware;
- (g) The linked CDPHE Data will be incorporated with data from other participating [REDACTED] [REDACTED] ("Study Data"). The Study Data will be maintained and analyzed by [REDACTED]. Upon termination of this Agreement, [REDACTED] will securely return or destroy CDPHE Data,

[REDACTED]

- (h) To ensure that any permitted agents and subcontractors to whom it provides CDPHE Data agree to the same restrictions and conditions that apply to [REDACTED] with respect to CDPHE Data;
- (i) To refrain from using CDPHE Data to identify or to contact individuals;
- (j) No PHI included in the CDPHE Data shall be publicly released. Any other release of information shall include substantially the following statement:

[REDACTED]

In addition, [REDACTED] shall notify CDPHE when the publication or presentation is available, and further, shall provide a copy of it to CDPHE upon request.

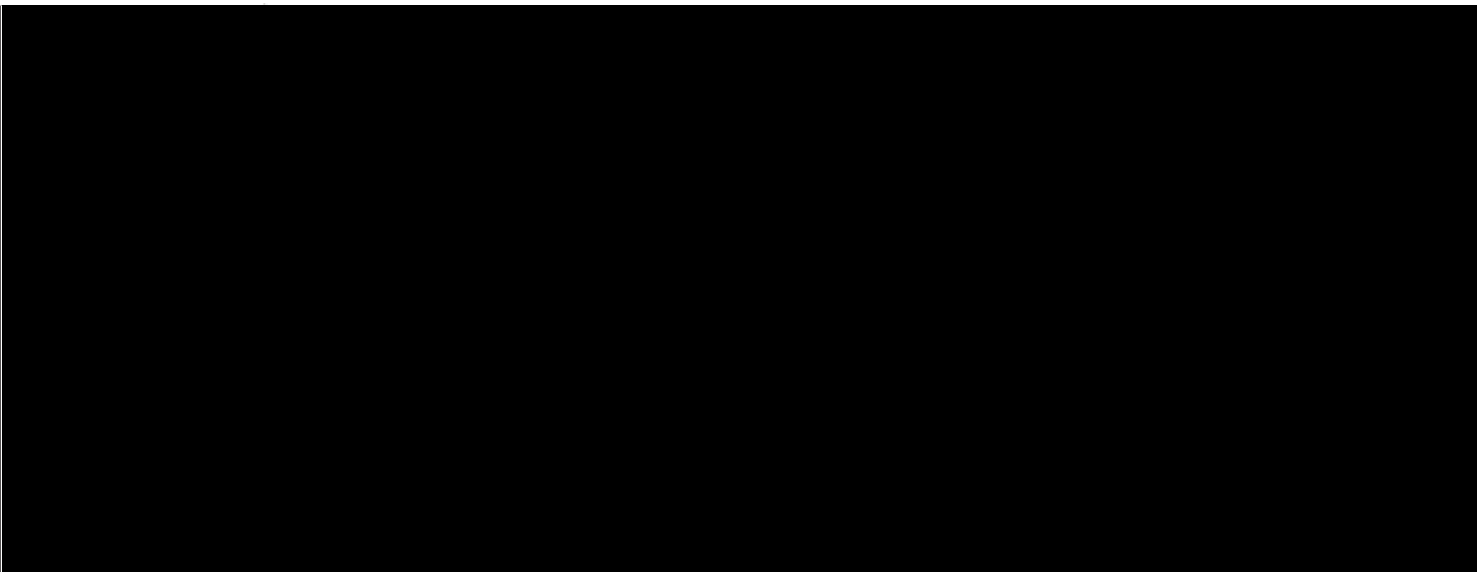
3. **Ownership of Data.** CDPHE Data is owned by CDPHE. [REDACTED] does not obtain any right, title, or interest in any of the CDPHE Data, except as otherwise specified in this Agreement. [REDACTED] Data is owned by [REDACTED] CDPHE does not obtain any right, title, or interest in any of the [REDACTED] Data, except as otherwise specified in this Agreement.
4. **IRB Approvals and Authorizations.** [REDACTED] agrees to furnish all documentation concerning IRB reviews and approvals to CDPHE upon request. [REDACTED] agrees to submit required documentation of any changes to the Protocol to an IRB prior to implementation of changes to the Protocol. [REDACTED] agrees to submit to CDPHE any change in Protocol, or any changes in either the waiver status or conditions for IRB approval of the Protocol directly related to the use of CDPHE Data upon request. [REDACTED] agrees to obtain individual authorizations for the Data it provides CDPHE,

unless its IRB approves a waiver of such an authorization. Documentation shall be provided by [REDACTED] prior to receipt of CDPHE Data.

5. **Breach or Violation.** In the event of a breach or violation of paragraphs 1 or 2 of this Agreement, a Party has the right to report the problem to the Secretary of Health and Human Services and to take other appropriate action, including but not limited to terminating this Agreement.
6. **Termination.** Either Party may terminate this Agreement with thirty (30) days written notice to the other Party's authorized official.
7. **No Warranties.** Except as provided below or prohibited by law, any Data delivered pursuant to this Agreement is understood to be provided "AS IS." [REDACTED] and CDPHE MAKE NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, [REDACTED] and CDPHE, to the best of their knowledge and belief, have the right and authority to provide their respective Data to each other for use in the Study.
8. **Liabilities.** Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the other Party's Data. The Discloser will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Discloser's Data by the Recipient.
9. **Amendments; Waiver.** This Agreement may not be modified, nor shall any provision hereof be waived or amended, except in a writing duly signed by authorized representatives of the Parties. A waiver with respect to one event shall not be construed as continuing, or as a bar to or waiver of any right or remedy as to subsequent events. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.
10. **Survival.** Paragraphs 1, 2, 3, 4, 5, 6, 7, and 8 will survive the expiration or termination of this Agreement. In addition, all other terms and conditions that by their nature are intended to extend beyond the expiration or termination of this Agreement, shall also survive the expiration or termination of this Agreement.

Remainder of page is intentionally left blank.

Signature of the Parties appear on the following page.



**Appendix A
Protocol**

(see attached pages)

Appendix B
Description of [REDACTED] Data

[REDACTED] will send CDPHE the following data elements, which constitute PHI as defined under HIPAA:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Appendix C
Description of CDPHE Data

CDPHE will send [REDACTED] the following data elements, which constitute a Limited Data Set as defined under HIPAA:

- Dates of diagnosis [month + year]

CDPHE will send [REDACTED] the following other data elements, which constitute De-Identified Data as defined under HIPAA:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]



Appendix D – STATEMENT OF WORK

Project Type:	Human Subjects Research
Project Name:	[REDACTED]
Project Objective(s):	[REDACTED]
[REDACTED] Deliverables:	[REDACTED]
CDPHE Deliverables:	[REDACTED]
Additional Tasks to Support Deliverables:	Once the linkage by CDPHE is complete, CDPHE will send the data to [REDACTED] CDPHE will notify [REDACTED] [REDACTED]
Timeline for Completion of Work:	[REDACTED]





Payment Costs/Terms:	[REDACTED]
Additional Information:	All paper data will be destroyed by shredding. Electronic data will be destroyed by using the most up to date software available at the time of study completion.

